

**REMARKS**

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-75 are pending in the subject application. Claims 38-43, 45 and 64-73 are withdrawn from consideration as the result of an Examiner's restriction requirement.

Claims 38-43, 45 and 64-73 are canceled and in view of the Examiner's earlier restriction requirement, Applicants reserve the right to present the above-identified withdrawn claims in a divisional application.

Claims 1-37, 46-63, 74 and 75 stand rejected under 35 U.S.C. §102, 35 U.S.C. §103, and/or 35 U.S.C. §112, second paragraph. Claim 44 was objected to as depending from a rejected base claim, however, the Examiner indicated that the claims would be allowable if appropriately re-written in independent form.

Claims 1, 52, 74 and 75 were amended to more distinctly claim Applicants' invention. Claims 1, 52 and 75 also were amended clarify that the force feedback mechanism is active.

Claims 2, 3 and 53 were amended to be consistent with the amended language of the related base claims.

Claims 3, 8, 10, 11-13, 15, 49, 61 and 63 so it was clear that the device referred to in the claims was the medical device.

Claims 7, 8, 63 and 74 were amended to clarify that the feedback was oscillatory. Also, claims 7 and 63 were amended to indicate that this oscillatory feedback to the user is to simulate device motion induced by simulated forces acting on the medical device, including but not limited to physiological forces such as patient breathing or cardiac action (e.g., heart motion).

Claim 8 also was amended to address the Examiner's non-art based rejections.

Claim 11 also was amended to clarify that the tracking unit is an optical tracking unit.

Claims 44 and 46 were amended to clarify that the syringe and balloon inflating device comprised the medical device.

Claims 54, 55 and 56 were amended to avoid possible antecedent basis concerns.

Claims 76 - 89 were added to further claim embodiments/ aspects of the present invention.

The amendments to the claims are supported by the originally filed disclosure (see for example pages 13, lines 5-7; pages 20-33, page 34, lines 15-25, and in Figures 13, 15 and 16).

**Claim 8 Is Rejected Under 35 U.S.C. § 112, Second Paragraph**

Claim 8 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinguish the invention. The Examiner states that there is insufficient antecedent basis for the claim because the claim depends on itself.

Applicants thank the Examiner for pointing out this inadvertent error and respectfully submit that the rejection is now moot in view of the amendment to the claim. Accordingly, Applicants request that the rejection be reconsidered and withdrawn.

**Claims 1-6, 9, 16-23, 25, 28, 33-35, 37, 47, 48, 52-55, 57, 58, 61, 62 and 75 Are Rejected Under 35 U.S.C. § 102 (b)**

Claims 1-6, 9, 16-23, 25, 28, 33-35, 37, 47, 48, 52-55, 57, 58, 61, 62 and 75 are rejected under 35 U.S.C. § 102 (b) as being anticipated by WO 99/38141 by Chosack ("Chosack") which the Examiner asserts identically discloses each of the elements of the claims.

Applicants submit that the rejection is moot in view of the amendment of the claims and traverse the rejection to the extent it would be applied to the amended claims.

The system according to the invention and the methods of using, as claimed, rely on the use of physically based modeling embodying finite element methods to simulate interactions

between a medical device and body cavity or lumen, providing highly realistic visual and tactile feedback when a user interacts virtually with the system to practice or implement a medical procedure. The physical properties of both the device and the lumen are taken into account by a computational engine or processor of the claimed invention in a physically based modeling procedure.

Chosack neither anticipates nor suggests the use of such physically based modeling embodying finite element methods. Although using animation to mimic certain processes such as blood flow and deformation, Chosack does not use a physically based finite element modeling system that calculates the amount of force that would be exerted as a result of interactions between a medical device and body cavity or lumen to provide force feedback to a user of the simulation system in addition to visual feedback; Chosack merely describes providing real-time visual feedback. Further, Chosack does not disclose altering the parameters of a finite element model of a device or body cavity or lumen in response to a user's interactions with the device, as recited in the newly added claims.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegel Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by the cited reference/admitted prior art.

Accordingly, because the reference does not teach each element of the claims as required under 35 U.S.C. § 102(b), Applicants respectfully submit that the rejection is improper and should be reconsidered and withdrawn.

**Claims 7, 8, 63 and 74 Are Rejected Under 35 U.S.C. § 103(a)**

Claims 7, 8, 63 and 74 are rejected under 35 U.S.C. § 103(a) as being obvious over Chosack in view of U.S. Patent 5,959,613 ("Rosenberg"). The Examiner acknowledges that Chosack does not disclose a system that provides continuous vibrational feedback to a user holding the device but asserts that Rosenberg discloses this feature in the context of an endoscope.

Applicant respectfully traverses the rejection. Neither Chosack nor Rosenberg teach the use of physically based modeling using finite element methods. In contrast to the present invention the secondary reference, Rosenberg, describes and teaches a method and apparatus for shaping force signals (i.e., an impulse-shaped force signal) for a force feedback mechanism. Thus, the secondary reference does not remedy the deficiency of Chosack and therefore the references combined do not disclose or suggest the invention.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the

teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding the disclosures of the cited references, there is no reasonable expectation of success provided in the reference(s). Also, it is clear from the foregoing discussion that the modification suggested by the Examiner would change the principle of operation of the device disclosed in the principal reference.

Accordingly, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

#### **Claims 12-15 Are Rejected Under 35 U.S.C. § 103(a)**

Claims 12-15 are rejected under 35 U.S.C. § 103(a) as being obvious over Chosack in view of U.S. Patent 6,610,007 B2 by Belson ("Belson"). The Examiner acknowledges that Chosack does not disclose a system that uses reflected light in a tracking mechanism but asserts that Belson discloses this limitation.

Applicant respectfully traverses the rejection. Neither Chosack nor Belson teach the use of physically based finite element modeling. Further, Belson does not disclose the use of perpendicular sensors nor provide any motivation to use such sensors. The secondary reference does not remedy the deficiency of Chosack and therefore the references combined do not disclose or suggest the invention.

Accordingly, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

#### **Claims 24 and 32 Are Rejected Under 35 U.S.C. § 103(a)**

Claims 24 and 32 are rejected under 35 U.S.C. § 103(a) as being obvious over Chosack in view of U.S. Patent 6,470,207 B1 by Simon ("Simon") and U.S. Patent 6,572,376 B1 by

Saunders (“Saunders”). The Examiner acknowledges that Chosack does not disclose a system a movable C-arm for a scanning device within scanning distance of the maniken or a foot pedal but asserts that Simon discloses this limitation. The Examiner cites Saunders for the general proposition that it is desirable to increase the realism of a simulation system by simulating actual devices.

Applicant respectfully traverses the rejection. Neither Chosack nor Simon nor Saunders teaches the use of physically based finite element modeling. The secondary reference does not remedy the deficiency of Chosack and therefore the references combined do not disclose or suggest the invention.

Accordingly, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**Claims 26, 27, 29 and 56 Are Rejected Under 35 U.S.C. § 103(a)**

Claims 26, 27, 29 and 56 are rejected under 35 U.S.C. § 103(a) as being obvious over Chosack in view of U.S. Patent 66,106,297 by Pollak, et al. (“Pollak”). The Examiner acknowledges that Chosack does not disclose a monitoring station comprising a second user interface device but asserts that Pollak discloses this limitation.

Applicant respectfully traverses the rejection. Neither Chosack nor Pollak teach the use of physically based finite element modeling. The secondary reference, Pollak, does not remedy the deficiency of Chosack and therefore the references combined do not disclose or suggest the invention.

Accordingly, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

**Claims 46, 49-51, 60 and 59 Are Rejected Under 35 U.S.C. § 103(a)**

Claims 46, 49-51, 60 and 59 are rejected under 35 U.S.C. § 103(a) as being obvious over Chosack in view of U.S. Patent 6,106,301 by Merrill ("Merril"). The Examiner acknowledges that Chosack does not disclose a system or method for simulating deployment of a balloon with a body cavity or lumen, simulation of minimally invasive procedures in blood vessels of the brain and heart or injection of a radio-opaque fluid but asserts that Merrill discloses or renders obvious this limitation.

Applicant respectfully traverses the rejection. Neither Chosack nor Merrill teach the use of physically based finite element modeling. The secondary reference, Merrill, does not remedy the deficiency of Chosack and therefore the references combined do not disclose or suggest the invention.

Further, none of the references disclose or suggest simulating blood vessels of the brain. The Examiner merely makes the conclusory statement that this would be an obvious step in view of Chosack and Merrill. As stated in Applicants previous Response, the blood vessels of the brain are much smaller, more fragile and more prone to spasm than the lumens of cardiovascular blood vessels. When a medical device is inserted in a blood vessel of the brain, because of this tendency to spasm, mere contact with the medical device will tend to cause the vessel to contract and prevent further movement of the device. Modeling of interactions between a device and lumen as required by claim 1 for example, requires modeling both properties of the blood vessels of the brain and the medical device. The disclosure of Merrill does not enable one of skill in the art to extrapolate from a simulation of cardiovascular blood vessels to simulation of blood vessels of the brain and/or interactions of a medical device with such blood vessels. Chosack, who simulates lumens of the gastrointestinal system, certainly does not provide such teaching.

Accordingly, in view of the above arguments, Applicants respectfully request that the rejection be reconsidered and withdrawn.

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#### **Claim 44**

Applicants note with appreciation the Examiner's acknowledgement that claim 44 is free of the prior art and would otherwise be allowable if rewritten as an independent claim.

As Applicants believe that the base claim is in a condition for allowance, Applicants have nor re-written claim 44 in independent form. Applicants, however, reserve the right to later amend the subject application so as to present claim 44 in independent form or to added an independent claim including the limitations of claim 44 as well as the associated base claim and any intervening claim(s).

#### **Claims 76 - 89**

As indicated above, claims 76 - 89 were added to further claim embodiments/ aspects of the present invention. These claims, as indicated herein, are clearly supported by the originally filed disclosure, including the originally filed claims. It also is respectfully submitted that these added claims are patentable over the cited prior art on which the above-described rejection(s) are based.

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Applicants believe that additional fees are not required for consideration of the within Response. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed

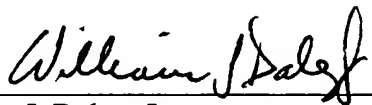


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for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit  
Account No. **04-1105**.

Respectfully submitted,  
Edwards & Angell, LLP

Date: June 8, 2004

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